Office of the Attorney General
Robert E. Cooper, Jr.

Department of Commerce and Insurance Commissioner
Leslie Newman

NEWS RELEASE

Office of the Attorney General
P.O. Box 20207 Nashville, TN 37202-0207

Department of Commerce and Insurance
Division of Consumer Affairs
500 James Robertson Parkway Nashville, TN 37243

FOR IMMEDIATE RELEASE
Aug. 30, 2007
#07-31

CONTACT:
Sharon Curtis-Flair
(615) 741-5860

HEART DEFIBRILLATOR MANUFACTURER ENTERS AGREEMENT WITH TENNESSEE, 35 OTHER STATES REGARDING FAULTY DEVICES

Tennessee has joined 35 other states in an agreement to resolve allegations a company allegedly continued to sell faulty heart pacemaker/defibrillator devices after learning of problems, Attorney General Bob Cooper and Director of the Division of Consumer Affairs Mary Clement announced today.

The agreement was signed with Guidant Corporation, a wholly owned subsidiary of Boston Scientific and one of the world's three largest manufacturers of Implantable Cardioverter Defibrillators (ICDs). ICDs are medical devices that doctors surgically implant in a patient's chest to monitor for abnormal heart rhythms. If the heart stops, the ICD delivers a small jolt of electricity to start the heart functioning again.

Guidant has agreed to implement certain ICD Safety programs, publicly report important safety information about the potentially life-saving heart devices it manufactures and pay $16,750,000 to the states. Up to $1,000,000 of the total will supplement Guidant's warranty program in order to compensate consumers. Tennessee's share is $390,000, which will be used to fund consumer education, various cardiac-related programs in the State Department of Health and costs associated with the investigation.

STATE'S INVESTIGATION

The states began investigating Guidant when they learned Guidant made changes in 2002 to correct Prizm's operation. If the device malfunctions, it allegedly could fail to deliver a life-saving jump-start to a patient's heart when needed. The States allege that Guidant continued to sell unmodified Prizms despite having made two separate changes to correct the faulty devices. Furthermore, the complaint alleges Guidant did not inform physicians or the public until May 2005 that it had continued to sell unmodified Prizms.

WARRANTY REFUND PROGRAM

Guidant is conducting a warranty program to provide consumers who wish to replace their Prizms with a new device at no cost and to reimburse consumers up to $2,500 for out-of-pocket expenses they incur with this replacement. Guidant has also agreed to extend the warranty program for an additional six months.

"We encourage Tennesseans who may have one of the devices in question to submit a claim within six months from today to receive warranty benefits," General Cooper said.

WHAT MODELS ARE COVERED BY THE WARRANTY REFUND PROGRAM

The ICD models of concern include: Ventak Prizm 2 DR ICD Model 1861 pacemaker, a CONTAK RENEWAL Model H135 device or a CONTAK RENEWAL 2 Model H155 device, which were implanted up to and including, July 2005.

FILING A WARRANTY REFUND CLAIM

Consumers should send their warranty supplement claims to the Tennessee Division of Consumer Affairs, Fifth Floor, 500 James Robertson Parkway, 37243-0600. Those claims should be in writing and include your name, address, phone number, what type of pacemaker you have, when it was implanted and what refund you are requesting or, in the past requested but were denied. In addition, you should include information about any direct, medical expenses or other costs you may have incurred but you were not previously reimbursed. You should include with your information any documentation such as bills, correspondence or notes regarding your claim.

OTHER TERMS OF THE SETTLEMENT

Among other terms, Guidant has agreed to:
*Establish a patient safety advisory board consisting of independent experts to evaluate data concerning ICD performance;
*Establish a patient safety officer position, staffed by a physician whose primary responsibility is to advance ICD patient safety;
*Clearly disclose and disseminate to the public specific information on a quarterly basis, including worldwide failure data, survival probability estimates, and current information in the event of an FDA recall of any ICD;
*Post a notice on its website within 30 days of any modification to any of its ICDs to correct a

failure pattern;
*Solicit the return of out-of-service ICDs; and,
*Maintain a data system to track the serial numbers, implant dates and explant dates of all ICDs Guidant distributes in the United States;

Under the terms of the settlement Guidant admits no wrongdoing.